



May 12, 2005

U.S. Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. 2004N – 0527

Dear Sir or Madame:

This letter represents the comments of the National Electrical Manufacturers Association (NEMA) on the direct final rule and companion proposed rule, 70 F. R. 9516, February 28, 2005 and 70 F.R. 9558, February 28, 2005, respectively, to amend the existing regulations for reporting of adverse events of medical devices. NEMA recommends that FDA withdraw the direct final rule and proceed with the usual procedures for notice and comment on the companion proposed rule.

NEMA is the largest U.S. trade association representing the U.S. electroindustry. The Diagnostic Imaging and Therapy Systems Division represents over ninety-five percent of the 7 billion dollar market for X-ray Imaging, Computed Tomography, Radiation Therapy, Nuclear Medicine Imaging, Diagnostic Ultrasound and Medical Imaging Informatics and Picture Archiving and Communications Equipment. NEMA appreciates the opportunity to share its views with you.

FDA states that its intent in revising the language of the existing regulation is to rewrite the rule into plain language and not to change the requirements in the existing MDR regulation 21 CFR 803. However, NEMA finds that the proposed rule is more restrictive with respect to who is qualified to make such a medical judgment regarding MDR reporting. The proposed rule specifically lists those persons authorized to make that judgment: physicians, nurses, risk managers and biomedical engineers. In contrast, the current regulation only lists the above occupations as examples of people qualified to make a medical judgment.

Specifically, Section 803.20 (c) (2) in the current regulation states,

*“Entities required to report under this part do not have to report adverse events for*

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*which there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur.”*

The proposed rule changes the text of this section to the following:

*“If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers.”*

This proposed change will limit user facilities/importers/manufacturers in their ability to make well-informed MDR reporting decisions. Device manufacturers, for example, often possess much more information than a healthcare professional with regard to the safety relevance of a specific incident, due to their extensive knowledge of the device as well as their experience with, and the prevalence of, a reported problem. To rely solely on the judgment of a health care professional, may result in misleading MDR reports, or worse, unreported incidents due to insufficient information. Furthermore, this change if adopted into the regulation would require all device importers/manufacturers to modify their current reporting procedures, employ a healthcare professional, and potentially disregard the extensive experience of their current MDR reporting staff.

NEMA believes that in addition to the examples cited by FDA in the proposed rule, other persons qualified to make these medical judgments would include “individuals with sufficient general product knowledge/experience, education, and/or training, to reach a reasonable conclusion regarding the reportability of the event.” This could include a number of individuals who are employed in various occupations by medical device manufacturers. NEMA recommends that the language of the proposed rule be changed to the following:

*“If you are a user facility, importer or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment (e.g., a physician, nurse, risk manager, or biomedical engineer) reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur.”*

We note in the Direct Final Rule that 21 CFR 803.55 (b) (9) and (b) (10), and 21 CFR 803.58, will remain stayed indefinitely, in accordance with the stays of effective date published in the Federal Registers of July 31, 1996 (61 FR 39868), and July 23, 1996 (61 FR 38346).

With respect to the requirements pertaining to baseline reports, particularly 21 CFR 803.55 (b) (9) and (b) (10), subsequent to the Final Rule on baseline reporting requirements issued on December 11, 1995, FDA received comments from industry that the requirements for denominator data were burdensome. As a result of these comments, FDA stayed the effective date of these requirements in a Final Rule issued on July 31, 1996, 61 FR 39868, stating that the agency required additional time to better understand methods used to derive denominator estimates, "to evaluate the rate of and relative impact of adverse events more accurately." FDA proposed conducting a future pilot program with the cooperation of industry to aid in this evaluation. NEMA believes that the current requirements of 21 CFR 803.55 (b) (9) and (b) (10) are unduly burdensome and thus agrees that these provisions should remain stayed indefinitely, until the value of such data can be fully analyzed and understood.

NEMA thanks FDA for allowing us to share our views on the proposed rule. We look forward to working with you.

If you have any questions regarding these comments, or require further clarification, please do not hesitate to contact me at (703) 841-3248.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard M. Eaton", with a stylized flourish at the end.

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